



## Complete Summary

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### TITLE

Informed consent: percentage of healthcare professionals who affirm that in their unit or area steps are always taken to ensure that patients have understood the risks and complications before they sign the informed consent form.

### SOURCE(S)

Ministry of Health. Safe practices indicators project: background, summary of methods and measurement strategies. Madrid: Ministry of Health; 2009 Feb 20. 97 p.

## Measure Domain

### PRIMARY MEASURE DOMAIN

Process

The validity of measures depends on how they are built. By examining the key building blocks of a measure, you can assess its validity for your purpose. For more information, visit the [Measure Validity](#) page.

### SECONDARY MEASURE DOMAIN

Does not apply to this measure

## Brief Abstract

### DESCRIPTION

This measure is used to determine the percentage of healthcare providers who affirm that in their unit or area steps are always taken to ensure that patients have understood the risks and complications before they sign the informed consent form.

The following survey item may be added to the "Safety Culture" survey instrument:

- "Before signing the informed consent form, patients or their representatives are asked to repeat their understanding of the explanations received regarding possible risks and complications of the intervention, exploration or treatment concerned."

Possible answer: never / almost never / sometimes / almost always / always

## **RATIONALE**

Informed consent should be viewed as an interactive process between healthcare providers and patients, not merely a form for which a signature must be obtained.

Main aim of indicator: to increase patient safety by improving communication between health professionals and patients. The rate should increase over time.

## **PRIMARY CLINICAL COMPONENT**

Informed consent form; patient understanding

## **DENOMINATOR DESCRIPTION**

Total number of healthcare professionals responding to the following item in the "Safety Culture" survey:

- "Before signing the informed consent form, patients or their representatives are asked to repeat their understanding of the explanations received regarding possible risks and complications of the intervention, exploration or treatment concerned."

Possible answer: never / almost never / sometimes / almost always / always

## **NUMERATOR DESCRIPTION**

Respondents indicating "always" x 100

## **Evidence Supporting the Measure**

### **EVIDENCE SUPPORTING THE CRITERION OF QUALITY**

- A formal consensus procedure involving experts in relevant clinical, methodological, and organizational sciences
- A systematic review of the clinical literature
- One or more research studies published in a National Library of Medicine (NLM) indexed, peer-reviewed journal

## **Evidence Supporting Need for the Measure**

### **NEED FOR THE MEASURE**

Overall poor quality for the performance measured  
Variation in quality for the performance measured

### **EVIDENCE SUPPORTING NEED FOR THE MEASURE**

Ministerio de Sanidad y Consumo. Indicadores de buenas practicas sobre seguridad del paciente. Resultados de su medicion en una muestra de hospitales del sistema nacional de salud Español. Madrid: Ministerio de Sanidad y Consumo; 2008. 95 p.

## State of Use of the Measure

### STATE OF USE

Current routine use

### CURRENT USE

Internal quality improvement

## Application of Measure in its Current Use

### CARE SETTING

Hospitals

### PROFESSIONALS RESPONSIBLE FOR HEALTH CARE

Advanced Practice Nurses  
Nurses  
Physicians

### LOWEST LEVEL OF HEALTH CARE DELIVERY ADDRESSED

Single Health Care Delivery Organizations

### TARGET POPULATION AGE

Unspecified

### TARGET POPULATION GENDER

Either male or female

### STRATIFICATION BY VULNERABLE POPULATIONS

Unspecified

## Characteristics of the Primary Clinical Component

### INCIDENCE/PREVALENCE

41.6 ± 1.5 of healthcare professionals affirm that in their unit or area steps are always taken to ensure that patients have understood the risks and complications before they sign the informed consent form.

## **EVIDENCE FOR INCIDENCE/PREVALENCE**

Ministerio de Sanidad y Consumo. Indicadores de buenas practicas sobre seguridad del paciente. Resultados de su medicion en una muestra de hospitales del sistema nacional de salud Español. Madrid: Ministerio de Sanidad y Consumo; 2008. 95 p.

## **ASSOCIATION WITH VULNERABLE POPULATIONS**

Unspecified

## **BURDEN OF ILLNESS**

Unspecified

## **UTILIZATION**

Unspecified

## **COSTS**

Unspecified

# **Institute of Medicine National Healthcare Quality Report Categories**

## **IOM CARE NEED**

End of Life Care  
Getting Better  
Living with Illness  
Staying Healthy

## **IOM DOMAIN**

Patient-centeredness

# **Data Collection for the Measure**

## **CASE FINDING**

Users of care only

## **DESCRIPTION OF CASE FINDING**

Total number of healthcare professionals responding to the following item in the "Safety Culture" survey:

- "Before signing the informed consent form, patients or their representatives are asked to repeat their understanding of the explanations received regarding possible risks and complications of the intervention, exploration or treatment concerned."

Possible answer: never / almost never / sometimes / almost always / always

## **DENOMINATOR SAMPLING FRAME**

Patients associated with provider

## **DENOMINATOR INCLUSIONS/EXCLUSIONS**

### **Inclusions**

Total number of healthcare professionals responding to the following item in the "Safety Culture" survey:

- "Before signing the informed consent form, patients or their representatives are asked to repeat their understanding of the explanations received regarding possible risks and complications of the intervention, exploration or treatment concerned."

Possible answer: never / almost never / sometimes / almost always / always

### **Exclusions**

None

## **RELATIONSHIP OF DENOMINATOR TO NUMERATOR**

All cases in the denominator are equally eligible to appear in the numerator

## **DENOMINATOR (INDEX) EVENT**

Diagnostic Evaluation  
Therapeutic Intervention

## **DENOMINATOR TIME WINDOW**

Time window is a single point in time

## **NUMERATOR INCLUSIONS/EXCLUSIONS**

### **Inclusions**

Respondents indicating "always" x 100

### **Exclusions**

None

## **MEASURE RESULTS UNDER CONTROL OF HEALTH CARE PROFESSIONALS, ORGANIZATIONS AND/OR POLICYMAKERS**

The measure results are somewhat or substantially under the control of the health care professionals, organizations and/or policymakers to whom the measure applies.

### **NUMERATOR TIME WINDOW**

Encounter or point in time

### **DATA SOURCE**

Clinician survey

### **LEVEL OF DETERMINATION OF QUALITY**

Individual Case

### **PRE-EXISTING INSTRUMENT USED**

"Safety Culture" survey instrument

## **Computation of the Measure**

### **SCORING**

Rate

### **INTERPRETATION OF SCORE**

Better quality is associated with a higher score

### **ALLOWANCE FOR PATIENT FACTORS**

Unspecified

### **STANDARD OF COMPARISON**

Internal time comparison

## **Evaluation of Measure Properties**

### **EXTENT OF MEASURE TESTING**

After pilot testing, the set of indicators has been measured in a random sample of 25 Spanish hospitals, stratified by hospital size. The main objective has been to field test the feasibility of measurement in the various settings representing real life situations in the context of the Spanish Health Care System.

Both the whole indicators validation report and the results of the baseline measurement in a sample of the Spanish National Health Service (NHS) hospitals may be accessed and downloaded from the Spanish Ministry of Health web page (in Spanish):

- [Validation report](#)
- [Results of baseline measurement in Spanish NHS hospitals](#)

## **EVIDENCE FOR RELIABILITY/VALIDITY TESTING**

Ministerio de Sanidad y Consumo. Construcción y validación de indicadores de buenas prácticas sobre seguridad del paciente. Madrid: Ministerio de Sanidad y Consumo; 2008. 178 p.

Ministerio de Sanidad y Consumo. Indicadores de buenas prácticas sobre seguridad del paciente. Resultados de su medición en una muestra de hospitales del sistema nacional de salud Español. Madrid: Ministerio de Sanidad y Consumo; 2008. 95 p.

Ministry of Health. Safe practices indicators project: background, summary of methods and measurement strategies. Madrid: Ministry of Health; 2009 Feb 20. 97 p.

## **Identifying Information**

### **ORIGINAL TITLE**

Percentage of healthcare professionals who affirm that in their unit or area steps are always taken to ensure that patients have understood the risks and complications before they sign the informed consent form.

### **MEASURE COLLECTION**

[Safe Practices Indicators Project](#)

### **MEASURE SET NAME**

[Facilitating Information Transfer and Clear Communication](#)

### **MEASURE SUBSET NAME**

[Understanding of Informed Consent](#)

### **SUBMITTER**

Spanish Agency for Healthcare Quality of the Spanish Ministry of Health

### **DEVELOPER**

Grupo de Investigación sobre Gestión de la Calidad en Servicios de Salud,  
University of Murcia, under contract to the Spanish Ministry of Health

### **FUNDING SOURCE(S)**

Agency for Quality, Spanish Ministry of Health

### **COMPOSITION OF THE GROUP THAT DEVELOPED THE MEASURE**

Saturno, Pedro J., MD, DrPH; Group Director and Project PI

Castillo, Carmen; López, M. José; Ramón, Teresa; Nurses

Carrillo, Andrés, MD; Intensive Care Specialist

Iranzo, M. Dolores; Hospital pharmacist

Soria, Victor, MD; Surgeon

Parra, Pedro, MD; Gomis, Rafael, MD; Gascón, Juan J., MD; Quality Management Specialists

### **FINANCIAL DISCLOSURES/OTHER POTENTIAL CONFLICTS OF INTEREST**

Project entirely financed by the Spanish Ministry of Health.

### **ADAPTATION**

Measure was not adapted from another source.

### **RELEASE DATE**

2009 Feb

### **MEASURE STATUS**

This is the current release of the measure.

### **SOURCE(S)**

Ministry of Health. Safe practices indicators project: background, summary of methods and measurement strategies. Madrid: Ministry of Health; 2009 Feb 20. 97 p.

### **MEASURE AVAILABILITY**

The individual measure, "Percentage of Healthcare Professionals Who Affirm that in Their Unit or Area Steps are Always Taken to Ensure that Patients have Understood the Risks and Complications Before They Sign the Informed Consent



Form," is published in "Safe Practices Indicators Project: Background, Summary of Methods and Measurement Strategies."

For more information, contact:

- Ministry of Health and Social Policy, Paseo del Prado, 18-20, planta baja, esquina con Lope de Vega. 28014 Madrid; Phone: +34 901 400 100; Fax: +34 915 96 44 80; Web site: [www.msc.es/en/home.htm](http://www.msc.es/en/home.htm).  
OR
- Pedro J. Saturno, Facultad de Medicina, Universidad de Murcia, 30100 Espinardo-Murcia (Spain); Phone: 868 883 948; Fax: +34 868 883947; E-mail: [psaturno@um.es](mailto:psaturno@um.es); Web site: <http://www.calidadsalud.com>.

## **COMPANION DOCUMENTS**

The following are available:

- Ministerio de Sanidad y Consumo. Construcción y validación de indicadores de buenas prácticas sobre seguridad del paciente. Madrid: Ministerio de Sanidad y Consumo; 2008. 178 p. This document is available in Portable Document Format (PDF) from the [Ministry of Health and Social Policy Web site](http://www.msc.es/en/home.htm) (in Spanish).
- Ministerio de Sanidad y Consumo. Indicadores de buenas prácticas sobre seguridad del paciente. Resultados de su medición en una muestra de hospitales del sistema nacional de salud Español. Madrid: Ministerio de Sanidad y Consumo; 2008. 95 p. This document is available in PDF from the [Ministry of Health and Social Policy Web site](http://www.msc.es/en/home.htm) (in Spanish).

## **NQMC STATUS**

This NQMC summary was completed by ECRI Institute on August 21, 2009. The information was verified by the measure developer on October 16, 2009.

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